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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,508	09/22/2000	Henry E. Young	1304-1-019CIP	1973

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EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

12

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,508

Applicant(s)

YOUNG ET AL.

Examiner

Thai-An N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/22/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Amendment, filed 5/22/03, Paper No. 11, has been entered. Claims 1-13 and 18-32 have been cancelled. Claims 14-17 are pending and under current examination.

Any rejection made of record in the prior Office action, mailed 11/20/02,, Paper No. 9, and not made of record in the instant Office action, has been withdrawn in view of Applicants' arguments and/or amendments to the claims.

Claim Objections

The prior objection of claim 15 because of the following informalities: the claim recites "likestem" in line 2 of the claim is *maintained*. It appears that the claim should read "like stem". Applicants argue that claim 15 has been cancelled by this Amendment (see p. 3 of the Response), however, it is noted that claim 15 currently pending. As such, appropriate correction is required.

Claim Rejections - 35 USC § 112

The prior rejections under 35 USC § 112, 2nd ¶ is moot in view of Applicants' cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The prior rejection of claims 14-17 under 35 U.S.C. 103(a) as being unpatentable over Pittenger *et al.* [Science, 284:143-147, 2 April 1999] in view of Sambrook *et al.* [Molecular Cloning, Book 3, 1989] is *maintained* for reasons of record.

The claims are directed to methods of producing genetically engineered pluripotent embryonic-like stem cells and genetically engineered stem cells, wherein the embryonic-like stem cell is derived from non-embryonic or postnatal

animal cells or tissue, capable of self-renewal and capable of differentiation to cells of endodermal, ectodermal and mesodermal lineages, genetically engineered to express a gene or protein of interest.

Claim 15 is a product-by-process claim. That is, that the pluripotent embryonic-like stem cell of the instant invention is "derived from" non-embryonic or postnatal animal cells or tissue. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Further, see MPEP §2113, "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *Pittenger* teach human mesenchymal stem cells which are

capable of differentiation into multiple mesenchymal lineages. As such, Pittenger teach pluripotent stem cells, as required by the claims.

Furthermore, with regard to claims 15-17, which are directed to methods for producing genetically engineered pluripotent embryonic-like stem cells, it is noted that although Applicants point to the specification for support for a description and definition of the claimed embryonic-like stem cells, this is not found persuasive. See pp. 3-4 of the Response. The specification provides the origin of the pluripotent embryonic-like stem cell [from postnatal or non-embryonic animal tissues or cells], however, the specification does not define the claimed cells such that they would be distinguished from other pluripotent stem cells known in the art.

Applicants argue, that with regard to the Pittenger reference, that the mesenchymal stem cells [MSCs] do not anticipate the claimed invention because, "Pittenger neither discloses every element of the rejected claims nor enables one skilled in the art to isolate or make the anticipating subject matter, specifically the claimed pluripotent embryonic-like stem cells." In particular, Applicants argue that the MSCs, as taught by Pittenger are found to differentiate into multiple mesenchymal lineages, and thus, by their very nature and character, these MSCs can **only** differentiate into mesoderm and **cannot** form cells or tissues of ectodermal or endodermal lineage [*emphasis in the original*]. Thus, Applicants conclude that the cells as taught by Pittenger are distinct from the present invention because Pittenger only teaches mesenchymal stem cells. See pp. 6-7 of the Response.

Applicants' arguments have been carefully considered, but they are not found to be persuasive. The claims recite that that pluripotent embryonic-like stem cells are, "capable of differentiation to cells of endodermal, ectodermal and mesodermal lineages." See claim 14. There is no requirement in the claims for the cells to be able to differentiate into all three of these lineages. As such, any teaching which shows differentiation into any one of these lineages would anticipate this claim. In the instant case, Pittenger shows that the MSCs are capable of differentiation into mesenchymal lineages, which would fulfill the requirements of the claims.

Pittenger teach human mesenchymal stem cells isolated from adult bone marrow which are found to differentiate into multiple mesenchymal lineages *in vitro* [see p. 143, 2nd column, 1st full paragraph]. Pittenger teach that these mesenchymal cells were characterized by their ability to proliferate in culture [see Figure 1]. Pittenger teach that the differentiation potential of the mesenchymal stem cells was tested by specific differentiation in adipogenic differentiation, chondrogenic differentiation and osteogenic differentiation under specific conditions [see pp. 144-145]. They differ from the claimed invention in that they do not teach transfecting the pluripotent embryonic stem-like stem cells with a DNA construct comprising at least one of a marker gene or a gene of interest.

However, prior to the time of the claimed invention, Sambrook teach methods of transfecting mammalian cells with any gene of interest [see 16.33-16.38]. Accordingly, in view of the combined teachings of Pittenger and Sambrook, it would

have been obvious for one of ordinary skill in the art at the time the claimed invention was made, to use the mesenchymal stem cells, as taught by Pittenger and transfect them with any DNA of interest, with a reasonable expectation of success. One of skill in the art would have been sufficiently motivated to make such a modification, as expression of proteins in mammalian cells can provide different purposes, as described by Sambrook on p. 16.3, such as for the expression of large amounts of protein of biological interest, or to study the biosynthesis and intracellular transport of proteins following their expression in various cell types.

Thus the claimed invention as a whole was clearly *prima facie* obvious at the time the claimed invention was made especially in the absence of sufficient, clear and convincing evidence to the contrary.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thái-An N. Ton
Patent Examiner
Group 1632

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
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